Kinser, Robin D.

From: Tricker, Anthony
Sent: Monday, May 07, 2001 4:43 AM
To: Kinser, Robin D.
Cc: Tricker, Anthony
Subject: RE: project 1164

Dear Robin,

Just a couple of minor comment:

Page 1.

After 'Components of Repeatability ..... Testing' there is an extra period which needs deleting

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Reproducibility Testing. I suggest that all participating laboratories not only receive 'splits' of the same sample for determination, but should also use the same standard stock solutions after appropriate dilution for calculation of results.

Page 3.

Please change my initial from T to A.

Best regards,
Tony

-----Original Message-----
From: **Kinser, Robin D.**
Sent: 4 mai 2001 01:30
To: Tricker, Anthony; Rustemeier, Klaus; Roemer, Ewald; remote Holt, Klaus von; Don Leyden (E-mail)
Cc: Kinser, Robin D.
Subject: project 1164

Dear Colleagues--

Although attempts I made to find a time when we could have a meeting were not successful, all of you have contributed to my work on Project 1164 (Repeatability and Reproducibility Assessment for Analytical Methods for Human Studies). The objective of this project is to "Develop a general approach for demonstrating repeatability and reproducibility of analytical methods to be utilized in Human Studies projects by May 15, 2001." The feedback you have provided me as we evaluated Covance draft protocols for validation and our one-on-one discussions of the outcomes of my discussions with other experts have been valuable as I drafted the attached document, which I view as the outcome for this project. Please review this draft and provide me with any comments you have by noon EDT on Friday, May 11. Don't hesitate to call or write if you wish to discuss any part of this memo with me. Keep in mind that the goal here was for a general approach, and we will always have the opportunity to amend this document if it becomes unworkable.

I am interested, of course, in all of your thoughts, but I have a few particular questions.

- Do you think I should include more detail in the definitions of components part, i.e. should I be defining accuracy and precision and stability?
- Should I give example acceptance criteria?
- Have I referenced INBIFO SOPs appropriately?

Please note that I intend to attach the FDA Draft Guidance for Bioanalytical Method Validation and have not done so on this copy. You can find it at http://www.fda.gov/cder/guidance/2578dft.pdf

Thanks again for your contributions to this endeavor so far. I look forward to receiving your comments at your earliest convenience. << File: reprepplan.doc >>

Robin

Robin Kinser
804-274-5905
Robin.D.Kinser@pmusa.com